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10/009,023	04/12/2002	Ian L Brown	28053/37955	6243

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[REDACTED] EXAMINER

FONDA, KATHLEEN KAHLER

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1623

DATE MAILED: 06/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/009,023	BROWN ET AL.
	Examiner Kathleen Kahler Fonda, Ph.D.	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 05 May 2003.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-33 and 36-38 is/are pending in the application.

4a) Of the above claim(s) 11-25 and 36-38 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-10 and 26-33 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 4-12-02 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.                    6) Other: \_\_\_\_\_.

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Applicant's election of Group I, claims 1-10, 26-33, and 35 in Paper No. 8 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-10 and 26-33 are treated on the merits herein, and claims 11-25 and 36-38 are withdrawn. Claims 34 and 35 have been canceled.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that

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was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 and 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over NOAKES et al. (U) in view of HITZ (A).

Applicant claims methods for regulating carbohydrate and fat metabolism; enhancing fat metabolism and utilization; reducing plasma leptin concentration and increasing satiety; treating an individual suffering from obesity; lowering the incidence or risk of obesity; lowering the incidence or risk of non-insulin dependent diabetes mellitus; reducing post-prandial glucose and/or insulin levels; and controlling an individual's body mass, by replacing at least 5% of an individual's daily carbohydrate intake with resistant starch, and at least 10% of the individual's saturated fat intake with unsaturated fat.

NOAKES presents a comparison of the effects of a diet in which approximately 25% of the carbohydrate is replaced by high-amylose starch (a resistant starch) in the diet of overweight hypertriglyceridemic subjects. NOAKES noted effects on plasma lipids, fasting and postprandial glucose, insulin profiles, and

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bowel function; see page 5. NOAKES does not teach replacing at least 10% of saturated fat with unsaturated fat.

HITZ teaches that diets high in mono-unsaturated fat and low in saturated fat may reduce "bad" or low-density lipoprotein cholesterol while maintaining "good" or high-density lipoprotein cholesterol; see column 2, lines 1-6.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to replace at least 10% of the saturated fat in the NOAKES diet with unsaturated fat. A worker of ordinary skill in the art at the time of the invention would have been motivated to do so in order to achieve the health benefits reported by HITZ. Insofar as each and every health benefit of the claims is not specifically disclosed in the references, it is considered that these would have been expected in view of the teachings of the prior art. Furthermore, the Examiner notes that the claims do not require administration to any particular class of patient. Thus, the benefits recited in the claims would necessarily occur upon administration of the diet suggested by the references.

No claim is allowed.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of

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the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://www.uspto.gov/ebc/index.html> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

  
Kathleen Kahler Fonda, Ph.D., J.D.  
Primary Examiner  
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